Sheet 1 of 1

Form PTO-1449 RMATION DISCLOSURE STATEMENT		Attorney's Docket No. ARR-0037-1 Application Serial No. 10/578,692			al No.		
INI	-ORMATIC	IN DISCLOSE	IKE STATEMENT		ajiv Nayar, et	ai.	
			_	Filing Date:		up Art Unit:	
	(use set	veral sheets i		August 26, 2006	165	2	
		<u> </u>	*	U.S. PATENT DOCUMENTS		T =	
Examin er Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date (if appropriate)
	1.	11/13/2003	2003/0211548	Packard, et al.			
	2.	07/25/2002	2002/0099013	Piccariello, et al.	,		
	3.	04/24/2003	2003/0078276	Andrianjara, et al.			
	4.	04/17/2003	2003/0073217 A1	Barr, et al.			
· · · · ·	5.	04/10/2003	2003/0068280	Bannister, et al.			
	6.	07/05/2001	2001/006939	Niven, et al.			
	7.	4/17/1979	4,150,071	Pecina			
	8.	4/22/1980	4,198,969	Virag			
	9.	3/3/1981	4,253,468	Lehmbeck			
	10.	11/24/1981	4,301,970	Craighero			
	11.	6/12/1984	4,453,542	Hughes			
	12.	7/8/1986	4,599,311	Kawasaki			
	13.	11/4/1986	4,620,670	Hughes			
	14.	12/8/1987	4,711,848	Insley, et al.			
	15.	03/22/1988	4,732,973	Barr, et al.	•		
	16.	06/01/1988	4,752,576	Brake, et al.			
	17.	10/1/1988	4,775,622	Hitzeman, et al.			
	18.	6/1/1989	4,837,148	Cregg			
·····	19.	6/1/1989	4,839,283	Kawasaki, et al.			
	20.	5/1/1990	4,929,555	Cregg, et al.			
	21.	6/5/1990	4,931,373	Kawasaki, et al.			
	22.	7/1/1990	4,940,661	Etcheverry, et al.			
	23.	4/1/1991	5,010,003	Chang, et al.			
	24.	5/1/1991	5,013,652	Straus berg, et al.			
	25.	3/3/1992	5,093,316	Lezdey,et al.			
	26.	5/19/2002	5,114,953	Galardy, et al.			
	27.	7/28/1992	5,134,119	Lezdey,et al.			
	28.	9/22/1992	5,150,071	Bouzidi			
	29.	11/24/1992	5,166,134	Lezdey, et al.			
	30.	6/8/1993	5,218,091	Kawasaki, et al.			
	31.	10/26/1993	5,256,657	Singh, et al.			
	32.	1/14/1997	5,594,106	Black, et al.			
	33.	4/8/1997	5,618,786	Roosdorp, et al.			
	34.	12/9/1997	5,696,147	Galardy			
	35.	6/30/1998	5,773,438	Levy, et al.			

EXAMINER:	DATE CONSIDERED:	

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

*If an asterisk is placed beside the reference number, a copy is not provided because the reference was previously cited by or submitted to the PTO in a prior application that is identical in the statement and relied upon for an earlier filing date under 35 U.S.C. §120. 37 C.F.R. §1.98 (d).

OIPE

SEP 0 4 2009

<i>/</i> . • .	E 400			·	1	057869		· 165; 8 (2/92) et 1 of 1
SEP U	4 2009 L	Form PTO-1	149	Attorney's Docket No. ARR-0037-1		lication Seria 578,692		etioni
TRAC	FILMATIO:	N DISCLOSU	IRE STATEMENT	Applicant(s)	1070	770,002		
-114.0	DAMATIO	11 01002000	149 IRE STATEMENT		Nayar, et a	al.		
	· · · · · · · · · · · · · · · · · · ·			Filing Date:		up Art Unit:		
	(use sev	eral sheets i	f necessary)	August 26, 2006	165	2		
	36.	07/14/1998	5,780,440	Lezdey, et al.				
	37.	4/6/1999	5,892,112	Levy, et al.				
	38.	7/1/1999	5,922,569	Heim, et al.				· ·
	39.	10/26/1999	5,972,986	Seibert, et al.				
	40.	11/30/1999	-5,993,783	Eljamal, et al.				
	41.	5/30/2000	6,068,994	Barr				
	42.	8/1/2000	6,103,500	Innis, et al.				
	43.	10/17/2000	6,133,304	Peterson, Jr., et al.				
	44.	3/1/2001	6,204,012	Hellmuth, et al.	<u> </u>			
	45.	07/2001	6,267,958 B1	Andya, et al				
	46.	10/22/2002	6,469,040	Seibert, et al.				
	47.	12/03/2002	6,489,308 B1	Shapiro, et al.	ļ			
	48.	4/8/2003	6,544,497	Zhu, et al.				
	49.	02/17/2004	6,693,096	Fritz, et al.				
	50.	5/25/2004	6,740,655	Magee, et al.				
	51.	08/27/2009	10/579,088	Kaufman C. Office Action				
	52.	11/16/2007	11/077,276	Kam, C.M. Office Action				
	53.	07/31/2008	11/077,276	Kam, C.M. Office Action				
	54.	01/13/2009	11/077,276	Kam, C.M. Office Action				
	55.	06/05/2009	11/077,276	Kam, C. M. Office Action		L,		
	, t. 3 , ,	i s		EIGN PATENT DOCUMENTS			-	•
Examin	Ref. No.	Date	Document No.	Name	Class	Subclass	Transla	
er							YES	NO
Initials	56.	09/28/1988	EP 0 284 044	EP				<u> </u>
	57.	11/02/1988	EP 0 289 336	EP				<u> </u>
	58.	07/31/2002	EP 0 648 838	EP	 			
	59.	10/02/2002	EP 1 047 450	EP				
	60.	07/31/2002	EP 1 226 136	EP	 			
	61.	12/27/1990	EP 73,654 A	EP				
	62.	06/15/2000	WO 00/34237	WO				
	63.	07/11/2002	WO 02/053138	WO			_	
	64.	08/22/2002	WO 02/064080	WO				· · · · · · · · · · · · · · · · · · ·
	65.	06/27/2002	WO 02/50287	WO			-	
<u></u>	66.	08/21/2003	WO 03/068188	WO	1			
····	67.	09/18/2003	WO 03/075959	WO			· · · · · · · · · · · · · · · · · · ·	
	68.	11/22/1984	WO 1984/04538	WO				
	69.	07/01/1999	WO 2004/103364	WO	_	1		
	70.	01/13/2005	WO 2005/003150	WO				

EXAMINER:	DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

*If an asterisk is placed beside the reference number, a copy is not provided because the reference was previously cited by or submitted to the PTO in a prior application that is identical in the statement and relied upon for an earlier filing date under 35 U.S.C. §120. 37 C.F.R. §1.98 (d).

SEP 0 1 2009

SEP 0	(با ۱۹۸۸ ۲							eet 1 of 1
JE THAD	.\$	Form PTO-1	449	Attorney's Docket No.		Application S	Serial No.	
TO THAD	BUARK	•		ARR-0037-1 10/578,692				
INF	ORMATIO	N DISCLOSU	IRE STATEMENT	Applicant(s)	Rajiv Nayar	, et al.		
	(1100.001	eral sheets i	f noogeeans)	Filing Date: August 26, 2006		Group Art Un	it:	
	71.	06/11/1992	WO 92/09282	I WO	<u>-</u>	1002		1
	71.	06/11/1992	WO 92/09556	wo				
	73.	06/11/1992	WO 92/09563	WO				+
	74.	07/22/1993	WO 93/13741	wo				
	75.	02/03/1994	WO 94/02446	wo				+
	76.	09/29/1994	WO 94/21625	wo				
	77.	10/13/1994	WO 94/22309	wo		-		+
	78.	04/13/1995	WO 95/09841	WO			··· - 	†
	79.	07/27/1995	WO 95/19965	wo				
	80.	05/30/1996	WO 96/16027	wo				1
	81.	11/13/1997	WO 97/42168	WO				
	82.	2/26/1998	WO 98/07742	wo				1
	83.	04/09/1997	WO 98/14424	wo				
	84.	10/8/1998	WO 98/43946	wo				1
	85.	10/29/1998	WO 98/47863	wo				1
	86.	09/10/1999	WO 99/44989	wo				1
								1
A. Sign			(includina	OTHER DOCUMENTS :	tc.)			
Examin er Initials	Ref. No.	Title						
	87.	2002.	,	naceuetical Additives, 2nd Edition, Sy				
	88.	Crit. Care M	Barnes, P.J., "Novel Approaches and Targets for Treatment of Chronic Obstructive Pulmonary Disease," <i>Am.J. Respir. Crit. Care Med.</i> , 160:S72-S79, 1999.					
	89.	Broach, et al., "Transformation in Yeast: Development of a Hybrid Cloning Vector and Isolation of the CAN1 Gene," Gene, 8:121-133, 1979.						
	90.	Carlson, J.A., et al., "Accumulation of PiZ α ₁ - Antitrypsin Causes Liver Damage in Transgenic Mice," J. Clin. Invest., 83:1183-1190, 1989.						
	91.		Carpenter, J.F., et al., "Rational Design of Stable Lyophilized Protein Formulations: Theory and Practice, Rational Design of Stable Protein Formulations Theory and Practice, 13: 109-133, 2002.					
	92.		Carrell, R.W., et al., Structure and Variation of Human Alpha 1-Antitrypsin," Nature, 298: 329-334, 1982.					
	93.	Carter, P., et <u>13(12)</u> : 4431	•	ucleotide Site-Directed Mutagenesis	Using M13	Vectors," Nuc	leic Acids Rese	arch,
	94.	Churg, et al.	, "Proteases and Emp	hysema," <i>Current Opinion in Pulmon</i>	ary Medicin	e, <u>11</u> : 153-159	, 2005.	
	95.	Cregg, et al. 1985.	, "Pichia Pastoris as a	Host System for Transformations," N	Molecular ar	nd Cellular Bio	ology, <u>5(12)</u> : 337	6-3385,

EXAMINER:	DATE CONSIDERED:				
EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in					
conformance and not considered. Include a copy of this form with next of	communication to applicant.				
*If an asterisk is placed beside the reference number, a copy is not provided because the reference was previously cited by or submitted to the					
PTO in a prior application that is identical in the statement and relied upo	on for an earlier filing date under 35 U.S.C. §120. 37 C.F.R. §1.98 (d).				

TNFORM	9/ 	Form PTO-1449	Attorney's Docket No. ARR-0037-1	Application Serial No. 10/578,692			
INFORM	IOITAN	N DISCLOSURE STATEMENT	Applicant(s)	Rajiv Nayar, et al.			
(u:	se seve	eral sheets if necessary)	Filing Date: August 26, 2006	Group Art Unit: 1652			
	96.	Das et al "Transformation of Kluw	veromyces Fragilis " Journal of B	acteriology, 158(3): 1165-1167, 1984.			
	97.			ria lipolytica," Current Genetics, 10: 39-48, 1985.			
	98.	Dayhoff, et al., "A Model of Evolutionary Change in Proteins," Atlas of Protein Sequence and Structure, National					
	99.	De Louvencourt, et al., "Transforma 154(2): 737-742, 1983.	ntion of Kluyveromyces lactic by k	iller Plasmid DNA," Journal of Bacteriology,			
	100.	du Preez, J.C., et al., "Transcription Recombinant Strains of Saccharom		β-xylanase Production by Ethanol in search, <u>1</u> : 233-240, 2001.			
	101.	Dycaico, et al., "Neonatal Hepatitis 1988.	Induced by α ₁ - Antitrypsin: A Trai	nsgenic Mouse Model," Science, <u>242</u> : 1409-1412,			
	102.	European Search Report dated Jan	uary 9, 2007.				
	103.	Gadek, et al., "α ₁ - Antitrypsin Deficiency," The Metabolic Basis of Inherited Diesease, Stanbury, J.B. et al., eds., McGraw-Hill, New York, pp. 1450-1467, 1982.					
	104.	Gaillardin, et al., "Integrative transfo	ormation of the Yeast Yarrowia lip	olytica," Current Genetics, <u>10</u> : 49-58, 1985.			
	105.	Colau, B., et al., "Revised sequence disclosed (1984), GenBank Accessi		A coding for human alpha 1-antitrypsin" as tabase: Genbank.			
	106.	Gleeson, M.A., et al., "Transformation Microbiology, <u>132</u> : 3459-3465, 1986.		nsenula polymorpha," Journal of General			
	107.	Hein, J "Unified Approach to Align	ment and Phylogenies," Methods	in Enzymology, <u>183</u> : 626-645, 1990.			
	108.	<u>128(1)</u> : 199-203, 1985.		heterogeneity," Biochem. Biophys. Res. Comm.,			
	109.	Higgins, D.G., et al., "Fast and Sens Communications, <u>5(2)</u> : 151-153, 198	9.	•			
	110.		·	USA, Genetics, <u>75(4)</u> : 1929-1933, 1978.			
	111.	Biotechology Prog, 17: 126-33, 2001	l .	a1-Antitrypsin from Cultured Plant Cells,"			
	112.	Cigarette Smokers," Am. Rev. Resp	ir. Dis., <u>128</u> : 833-838, 1983.	Accumulation of Neutrophils in the Lungs of			
	113.	Ito, H., et al., "Transformation of Inta 168, 1983.	act Yeast Cells Treated with Alkal	Cations", Journal of Bacteriology, <u>153(1)</u> : 163-			
	114.			ples," Interpharm Press, pp. 42-44, 261-279, 1999.			
	115.	Jones, E.W., "Tackling the Protease	Problem in Saccharomyces Cere	visiae," Methods in Enzymology, <u>194</u> : 428-453,			

DATE CONSIDERED: EXAMINER:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

*If an asterisk is placed beside the reference number, a copy is not provided because the reference was previously cited by or submitted to the PTO in a prior application that is identical in the statement and relied upon for an earlier filing date under 35 U.S.C. §120. 37 C.F.R. §1.98 (d).

10578692 ~ GAU: 1652 PTO/SB/08 (2/92) Sheet 1 of 1

| Structure | Structure | Sheet |

SEP II & LOUD !	Form PTO-1449	Attorney's Docket No.	Application Serial No.		
TO-1449 THEORY ATION DISCLOSURE STATEMENT		ARR-0037-1	10/578,692		
ANTORMATION DISCLOSURE STATEMENT		Applicant(s)			
•		Rajiv Nayar, et al.			
		Filing Date:	Group Art Unit:		
(use sev	eral sheets if necessary)	August 26, 2006	1652		
116.	, ,	·	," Methods in Enzymology, 85(31):372-386, 1990.		
117.	Candidate: TBV25H Expressed in Ye 1994.	east and Purified Using Nickel-NTA	Malaria Transmission-Blocking Vaccine Agarose," Nature Publishing Group, <u>12</u> : 494-499,		
118.	Kunze, et al., "Transformation of the of Basic Microbiology, <u>25(2)</u> : 141-14		dida maltosa and Pichia guilliermondii," Journal		
119.	Kurachi, K., et al., "Cloning and Seq 78(11): 6826-6830, 1981.	uence ofcDNA Coding for a ₁ -Antitr	rypsin," Proc Natl Acad Sci USA, Biochemistry,		
120.	Copies of Mature α-Factor," Cell, <u>30</u>	: 933-943, 1982.	ative α-Factor Precursor Contains Four Tandem		
121.	Kurtz, M.B., et al., "Integrative Trans and Cellular Biology, <u>6(1)</u> : 142-149,		ing a Cloned Candida ADE2 Gene," Molecular		
122.	Ljujic, et al., "Screening of alpha-1-antitrypsin gene by denaturing gradient gel electrophoresis (DGGE)", J. Biochem. Biophys. Meth., 68(3) 167-173, (2006)				
123.			in the Liver," Nature, <u>357</u> : 605-607, 1992.		
124.	Luisetti, et al., "Alpha-1-antitryspin (169, (2004)	deficiency 1: Epidemiology of alph	a 1-antitryspin deficiency", Thorax, 59 (2): 164-		
125.	Myers, E.W., et al. "Optimal Alignme	ents in Linear Space," CABIOS Con	nmunications, <u>4(1)</u> : 11-17, 1988.		
126.	Nail, S., et al., "Development and Manufacture of Protein Pharmaceuticals," Pharmaceutical Biotechnology, 14: 65-66, 2002.				
127.	Two Proteins," J. Mol. Biol., 48: 443-	-453, 1970.	or Similarities in the Amino Acid Sequence of		
128.	Noronha, S.B., et al., "Transition Phase in the Production of Recombinant Proteins in Yeast Under the ADH2 Promoter: An Important Step for Reproducible Manufacturing of a Malaria Transmission Blocking Vaccine Candidate," Journal of Individual Microbiology & Biotechnology, 20:192-199, 1998.				
129.	O'Connor, G.M., "Design and Evalua Bioengineering, <u>39 (3)</u> :293-304, 1992		Cell Density Fermentations," Biotechnology and		
130.	Pemberton, P., et al., "Inhaled recon the Mouse," COPD: Journal of Chro		orates Cigarette Smoke-Induced Emphysema in e, <u>3</u> : 101-108, 2006.		
131.	Rabe, "Outcome Measures in COPD				
132.	Practice, Pharmaceutical Biotechno	logy, Kluwer Academic/Plenum Pu			
133.	Robinson, D.F., "Comparison of Lab 119,1971.	peled Trees with Valency Three," Jo	ournal of Combinational Theory, 11: 105-		
134.	Roche, N., et al., "Current Issues in 229, 1997	the Management of Chronic Obstr	uctive Pulmonary Diseases," Respirology, 2: 215-		

EXAMINER:	DATE CONSIDERED:
•	

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

*If an asterisk is placed beside the reference number, a copy is not provided because the reference was previously cited by or submitted to the PTO in a prior application that is identical in the statement and relied upon for an earlier filing date under 35 U.S.C. §120. 37 C.F.R. §1.98 (d).

147.	Travis, et al., "Isolation and Properties of Recombinant DNA Produced Variants of Human Alpha1-Proteinase Inhibitor," Journal of Biological Cheimstry, <u>260(7):</u> 4384-4389, 1985.
148.	Tuite, M.F., et al., "Regulated High Efficiency Expression of Human Interferon-Alpha in Saccharomyces cerevisiae," The EMBO Journal, 1(5): 603-608, 1982.
149.	Van Den Berg, et al., "Kluyveromyces as a Host of Herterologous Gene Expression: Expression and Secretion of Prochymosin", Biotechnology, <u>8</u> : 135-140, 1990.
150.	Van Steenbergen, "Alpha 1-antitrypsin deficiency: an overview, Acta. Clin. Belg., 48(3): 171-189, (1993)
151.	Wells, J.A., "Cassette Mutagenesis: An Efficient Method for Generation of Multiple Mutations at Defined Sites, et al., Gene, 34: 315-323, 1985.
152.	Wells, J.A., et al., "Importance of Hydrogen-Bond Formation in Stabilizing the Transition State of Sutilisin, Philos Trans. R. Soc. London, 317: 415-423, 1986.
153.	Wilbur, W.J., et al., "Rapid Similarity Searches of Nucliec Acid and Protein Data Banks," Proc Natl Acad of Sci USA, 80:
EXAMINER:	DATE CONSIDERED:
	f citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in ot considered. Include a copy of this form with next communication to applicant.

'if an asterisk is placed beside the reference number, a copy is not provided because the reference was previously cited by or submitted to the PTO in a prior application that is identical in the statement and relied upon for an earlier filing date under 35 U.S.C. §120. 37 C.F.R. §1.98 (d).

JU (5)					
\$ E	Form PTO-1449	Attorney's Docket No.	Application Serial No.		
NFORMATI		ARR-0037-1	10/578,692		
NFORMATI	ON DISCLOSURE STATEMENT	Applicant(s)			
		F	Rajiv Nayar, et al.		
		Filing Date:	Group Art Unit:		
(use se	everal sheets if necessary)	August 26, 2006	1652		
	726-730, 1983.				
154		l			
155	in Homogygous PiZZ α1-Antitrypsir	Wu, Y., et al., "A Lag in Intracellular Degradation of Mutant α1-Antitrypsin Correlates with the Liver Disease Phenotype in Homogygous PiZZ α1-Antitrypsin Deficiency," Proc. Natl. Acad. Sci., 91: 9014-9018, 1994.			
156	Zakian, V.A., et al., "Construction, Replication, and Chromatin Structure of TRP1 R1 Circle, a Multiple-Copy Synthetic Plasmid Derived from Saccharomyces cerevisiae Chromosomal DNA", Molecular and Cellular Biology, 2(3): 221-232, 1982.				
157	Zoller, et al., "Oligonucleotide-Directed Mutagenesis Using M13-Derived Vectors: An Efficient and General Procedure for the Production of Point Mutations in any Fragment of DNA," Nucleic Acids Research, 10(20): 6487-6500, 1982.				
158		umor-Suppressing Activity in Huma	in Mamary Epithelial Cells," Science, <u>263</u> : 526-		

EXAMINER: /Sheridan Swope/	DATE CONSIDERED: 10/27/2009
EXAMINER: Initial if citation considered, whether or not the citation conf	orms with MPEP 609. Draw a line through the citation if not in

conformance and not considered. Include a copy of this form with next communication to applicant.

*If an asterisk is placed beside the reference number, a copy is not provided because the reference was previously cited by or submitted to the PTO in a prior application that is identical in the statement and relied upon for an earlier filing date under 35 U.S.C. §120. 37 C.F.R. §1.98 (d).